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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/806,952      | 04/05/2001  | Olivier Lavergne     | 427.046             | 9561             |

7590 08/03/2004

Bierman Muserlian and Lucas  
600 Third Avenue  
New York, NY 10016

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| EXAMINER |
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DESAI, RITA J

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| ART UNIT | PAPER NUMBER |
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1625

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/806,952

Applicant(s)

LAVERGNE ET AL.

Examiner

Rita J. Desai

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 5/4/2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 5, 24, 26 and 27.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_



Rita J. Desai  
Primary Examiner  
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## Addendum to the Advisory Action

The claims 5, 24, 26 and 27 are pending.

Applicants arguments are not found to be persuasive.

Applicants respectfully traverse this ground of rejection since it is deemed that the combination of the references, which the Examiner has made with the benefit of Applicants' disclosure, would in no way suggest to one skilled in the art Applicants' novel compounds and their use. The Hauseer et al reference teaches cpt compounds wherein  $R_1$  has a wide variety of substituents.  $R_1$  could be acyl of an alkanic acid, alkenic acid, alkynyl acid or an aryl acid or  $R_1$  could be alkenyl or alkynyl optionally substituted with at least one halogen hydroxyl group, alkyl or alkoxy group or  $R_1$  could be halo-oxo or  $-S-R_3$  or  $-S(O)-alkyl$  or  $-OSO_2CF_3$  or  $-SiR_8R_9$  and  $R_{10}$  or  $-R_5-SiR_8, R_9$  and  $R_{10}$  or  $-S-R_5-SiR_8R_9$  and  $R_{10}$  and it is stated that all these groups can assist in making the cpt compounds more soluble. There is no teaching of any specific Si substituent and there is advantage over the other compounds.

The examiner repeats that the WO 98/07727 does clearly disclose the Si substituted group at the same location but on a cpt.

Lavergne teaches that hcpt is better than cpt. [the genus clearly encompasses the Lavergne substituents. ]

Thus it would be obvious to modify the cpt Si substituted to the hpct Si group substituted analogs.

See below :

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However the rejection of claims 5, 24, 26 and 27 under 35USC 103 over Hauseer WO98/07727 and Oliver Lavergne et al still stands.

Applicants claim that examiner has manufactured the prior art is incorrect.

Hauseer '727 clearly teaches the Si containing group on the same position, but on a camptothecin.

Lavergne et al even though submitted by the applicant in the 1449 clearly teaches that homocamptothecin is more stable. Not only that but in the arguments submitted on 9/12/03 paper # 15 applicants clearly indicate not only the equivalence of hcpt and cpt but that hcpt is better, more effective and more stable than the cpt!!

The cancer search Vol 59, Laurence Ginot clearly teaches that hcpt is more efficacious than cpt.

The Biochemistry 1999 Vol 38 pages 15556-15563 Bailly et al also clearly teaches that the lactone cleavage is different in the cpt and hcpt and hcpt is more stable and that the highly reactive lactone is not essential for topoisomerase I-mediated anticancer activity.

Thus applicants own arguments strengthen the teachings of Lavergne et al and makes the rejection even more obvious.

Thus the rejection stands.

The cpt and hcpt are different compounds but the activity has a correlation as taught by the reference and that hcpt is superior in activity.

Since WO '927 teaches the Si containing group as being more lipophylic, it would be obvious since the motivation to make hcpt more lipophylic for even better activity is clearly obvious.

The rejection still stands.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R.D.  
August 2, 2004

Rita J. Desai  
Primary Examiner  
Art Unit 1625  
  
8/2/04